Kim, Jung Woo, Seoul, Korea, Republic of
Choi, Nam Hee, Seoul, Korea, Republic of
Shin, Hee Jong, Kyeonggi-do, Korea, Republic of
Yang, Su Geun, Kyeonggi-do, Korea, Republic of
PATENT ASSIGNEE(S): Chong Kun Dang Corp., Korea, Republic of (non-U.S. corporation)

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 6063762		20000516
APPLICATION INFO.:	US 1998-146584		19980903 (9)

	NUMBER	DATE
PRIORITY INFORMATION:	KR 1997-66454	19971205
	KR 1998-10046	19980324
	KR 1998-15309	19980429
	KR 1998-24207	19980625

DOCUMENT TYPE: Utility
FILE SEGMENT: Granted
PRIMARY EXAMINER: Moezie, F. T.
LEGAL REPRESENTATIVE: Heslin & Rothenberg, P.C.
NUMBER OF CLAIMS: 25
EXEMPLARY CLAIM: 1
NUMBER OF DRAWINGS: 1 Drawing Figure(s); 1 Drawing Page(s)
LINE COUNT: 1050
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

CLM What is claimed is:

1. A cyclosporin-containing microemulsion preconcentrate composition which comprises: 1) a cyclosporin as an active ingredient; 2) a lipophilic solvent chosen from the group consisting of triacetin, triethyl citrate, tributyl citrate, acetyltributyl citrate and acetyltriethyl citrate; 3) an oil; and 4) a surfactant wherein the cyclosporin, lipophilic solvent, surfactant and oil are present in the mixing ratio of 1:0.1-5.0:2-10:0.1-5.0, on the basis of weight.

2. A composition according to claim 1, wherein the said cyclosporin is cyclosporin A.

3. A composition according to claim 1, wherein the lipophilic solvent is triacetin.

4. A composition according to claim 1, wherein the said oil is at least one member selected from the group consisting of a vegetable oil; and esterification product of vegetable oil; an animal oil and derivatives thereof, and an unsaturated long chain fatty acid.

5. A composition according to claim 4, wherein the said vegetable oil is a refined vegetable oil.

6. A composition according to claim 5, wherein the said refined vegetable oil is at least one member selected from Super-refined forms of corn oil, borage oil, sesame oil, primrose oil, peanut oil and olive oil.

7. A composition according to claim 4, wherein the said esterification product of vegetable oil is i) a product from esterification of vegetable oil with glycerin; ii) a product from esterification of vegetable oil with monohydric alcohol; iii) a product from esterification of vegetable oil with triacetin; and iv) a product from esterification of vegetable oil with polyglycerol.

8. A composition according to claim 7, wherein the said product from esterification of vegetable oil with glycerin is fatty acid

triglycerides; monoglycerides; mono-and di-glycerides; or a mixture of two thereof.

9. A composition according to claim 8, wherein the said fatty acid triglyceride is C.sub.8 .about.C.sub.12 fatty acid medium chain triglyceride.

10. A composition according to claim 8, wherein the said mono- and di-glycerides is C.sub.16 .about.C.sub.18 fatty acid mono- and di-glycerides.

11. A composition according to claim 7, wherein the said product from esterification of vegetable oil with monohydric alcohol is a product from esterification of borage oil or olive oil with monohydric alcohol.

12. A composition according to claim 7, wherein the said product from esterification of vegetable oil with monohydric alcohol is at least one member selected from the group consisting of ethyl oleate, ethyl linoleate, isopropyl palmitate and isopropyl myristate.

13. A composition according to claim 7, wherein the said product from esterification of vegetable oil with triacetin is C.sub.14 .about.C.sub.20 fatty acid mono- and di-acetylated monoglyceride.

14. A composition according to claim 7, wherein the said product from esterification of vegetable oil with polyglycerol is an oil formed from esterification of fatty acid with di-, tetra-, hexa- or deca-glycerol.

15. A composition according to claim 4, wherein the said animal oil and derivative thereof is at least one component selected from the group consisting of squalenes; omega-3 essential fatty acid; oils formed from the esterification of omega-3 essential fatty acid with monohydric alcohol; and oils of triglyceride form of omega-3 essential fatty acid.

16. A composition according to claim 1, wherein the said surfactant has HLB value of 1.about.20.

17. A composition according to claim 16, wherein the said surfactant is at least one member selected from the group consisting of polyoxyethylene glycolated natural or hydrogenated vegetable oils; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene fatty acid esters; polyoxyethylene-polyoxypropylene co-polymers; polyoxyethylene-polyoxypropylene block co-polymers; dioctylsuccinate, dioctyl sodium sulfosuccinate, di-[2-ethylhexyl]-succinate or sodium lauryl sulfate; phospholipids; bile salts; trans-esterification products of natural vegetable oil triglycerides and polyalkylene polyols; mono-, di- and mono/di-glycerides; sorbitan fatty acid esters; pentaerythritol fatty acid esters and polyalkylene glycol ethers, and pentaerythrite fatty acid esters; sterols and derivatives thereof; polyethylene glycol 660 12-hydroxystearate; polyethylene glycol fatty acid esters; and di-.alpha.-tocopheryl polyethylene glycol 1000 succinate.

18. A composition according to claim 17, wherein the said surfactant is at least one member selected from the group consisting of polyoxyethylene glycolated natural or hydrogenated vegetable oils; polyoxyethylene sorbitan fatty acid esters; trans-esterification products of natural vegetable oil triglycerides and polyalkylene polyols; and polyethylene glycol fatty acid esters.

19. A composition according to claim 18, wherein the said surfactant is at least one member selected from the group consisting of polyoxyethylene glycolated natural or hydrogenated vegetable oils; and polyoxyethylene sorbitan fatty acid esters.

20. A composition according to claim 1, wherein the said cyclosporin, the said lipophilic solvent, the said surfactant and the said oil component are present in the mixing ratio of 1:1-3:3-8:1-3, on the basis of weight.

21. A composition according to claim 1, wherein it further comprises at least one species of pharmaceutically acceptable additives selected from the group consisting of antioxidant, viscosity control agent, dissolution control agent, flavor, preservatives and coloring agents.

22. A pharmaceutical formulation comprising the composition according to claim 1, wherein the dosage form is a soft capsule, a hard capsule sealed with a gelatin banding at the conjugated portion, or an oral liquid preparation.

23. A composition according to claim 19, wherein the surfactant is a polyoxyethylene glycolated natural or hydrogenated vegetable oil.

24. A composition according to claim 23, wherein the surfactant is a polyoxyethylene glycolated natural or hydrogenated castor oil.

25. A composition according to claim 1, comprising: 1) cyclosporin A as an active ingredient; 2) triacetin as a lipophilic solvent; 3) a C.sub.8-12 fatty acid medium chain triglyceride as an oil; and 4) a polyoxyethylene glycolated natural or hydrogenated castor oil as a surfactant.

L10 ANSWER 3 OF 3 USPATFULL

ACCESSION NUMBER:	2000:21561 USPATFULL
TITLE:	Cyclosporin-containing microemulsion preconcentrate composition
INVENTOR(S):	Hong, Chung Il, East Amherst, NY, United States Kim, Jung Woo, Seoul, Korea, Republic of Choi, Nam Hee, Seoul, Korea, Republic of Shin, Hee Jong, Kyeonggi, Korea, Republic of Yang, Su Geun, Kyeonggi-do, Korea, Republic of
PATENT ASSIGNEE(S):	Chong Kun Dang Corp., Korea, Republic of (non-U.S. corporation)

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 6028067		20000222	
APPLICATION INFO.:	US 1998-67363		19980427	(9)

	NUMBER	DATE
PRIORITY INFORMATION:	KR 1997-66454	19971205
	KR 1998-10046	19980324

DOCUMENT TYPE:	Utility
FILE SEGMENT:	Granted
PRIMARY EXAMINER:	Weddington, Kevin E.
LEGAL REPRESENTATIVE:	Heslin & Rothenberg, P.C.
NUMBER OF CLAIMS:	21
EXEMPLARY CLAIM:	1
NUMBER OF DRAWINGS:	1 Drawing Figure(s); 1 Drawing Page(s)
LINE COUNT:	862

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

CLM What is claimed is:

1. A cyclosporin-containing pharmaceutical composition, said composition adapted for oral administration as a microemulsion preconcentrate and comprising: 1) a cyclosporin as an active ingredient; 2) a lipophilic solvent chosen from an alkyl ester of polycarboxylic acid and a carboxylic acid ester of polyols; 3) an oil; and 4) a surfactant.

2. A composition according to claim 1, wherein said cyclosporin is cyclosporin A.

3. A composition according to claim 1, wherein said alkyl ester of polycarboxylic acid is at least one member selected from the group consisting of triethyl citrate, tributyl citrate, acetyltributyl citrate, and acetyltriethyl citrate.

4. A composition according to claim 1, wherein said carboxylic acid ester of polyols is triacetin.

5. A composition according to claim 1, wherein said oil is at least one member selected from the group consisting of vegetable oil and/or the esterification product of fatty acid.

6. A composition according to claim 5, wherein said vegetable oil is refined vegetable oils.

7. A composition according to claim 6, wherein said refined vegetable oil is refined-form of corn oil, borage oil, sesame oil, primrose oil, peanut oil and olive oil.

8. A composition according to claim 5, wherein the esterification product of fatty acid contained in vegetable oil is i) the product from esterification of fatty acid with glycerin; ii) the product from esterification of fatty acid with monohydric alcohol; and iii) the product from esterification of fatty acid with triacetin.

9. A composition according to claim 8, wherein said product from esterification of fatty acid with glycerin is fatty acid triglyceride; and/or mono- and di- glyceride.

10. A composition according to claim 9, wherein said fatty acid triglyceride is a C.sub.8 .about.C.sub.12 fatty acid medium chain triglyceride.

11. A composition according to claim 9, wherein said mono- and di-glyceride is a C.sub.16 -C.sub.18 fatty acid mono- and di-glyceride.

12. A composition according to claim 8, wherein said product from esterification of fatty acid with monohydric alcohol is at least one member selected from the group consisting of ethyl oleate, ethyl linoleate, isopropyl palmitate and isopropyl myristate.

13. A composition according to claim 8, wherein said product from esterification of fatty acid with triacetin is a C.sub.14 -C.sub.20 fatty acid diacetylated monoglyceride.

14. A composition according to claim 1, wherein said oil further comprises unsaturated long chain fatty acids.

15. A composition according to claim 1, wherein said surfactant has HLB value of 1.about.20.

16. A composition according to claim 15, wherein said surfactant is at least one member selected from the group consisting of polyoxyethylene glycolated natural or hydrogenated vegetable oils; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene fatty acid esters; polyoxyethylene-polyoxypropylene co-polymers; polyoxyethylene-polyoxypropylene block co-polymers; dioctylsuccinate, dioctyl sodium sulfosuccinate, di-[2-ethylhexyl]-succinate or sodium lauryl sulfate; phospholipids; bile salts; trans-esterification products of natural vegetable oil triglycerides and polyalkylene polyols; mono-, di- and

mono/di-glycerides; sorbitan fatty acid esters; pentaerythritol fatty acid esters and polyalkylene glycol ethers; and sterols and derivatives thereof.

17. A composition according to claim 16, wherein said surfactant is at least one member selected from the group consisting of polyoxyethylene glycolated natural or hydrogenated vegetable oils; trans-esterification products of natural vegetable oil triglycerides and polyalkylene polyols; and lecithins.

18. A composition according to claim 1, wherein said cyclosporin, said lipophilic solvent, said surfactant and said oil component is present in the mixing ratio of 1:0.1.about.5:2.about.10:0.1.about.5 on the basis of weight.

19. A composition according to claim 18, wherein said cyclosporin, said lipophilic solvent, said surfactant and said oil component is present in the mixing ratio of 1:1.about.3:3.about.8:1.about.3 on the basis of weight.

20. A composition according to claim 1, wherein it further comprises at least one species of pharmaceutically acceptable additives selected from the group consisting of antioxidant, viscosity control agent, dissolution control agent, flavor, preservatives and coloring agents.

21. A pharmaceutical formulation comprising the composition according to claim 1, wherein the dosage form is chosen from a soft capsule, a hard capsule sealed with a gelatin banding at the conjugated portion, and an oral liquid preparation.

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L10 ANSWER 1 OF 3 USPATFULL
ACCESSION NUMBER: 2001:107866 USPATFULL
TITLE: Emulsion preconcentrate comprising a **cyclosporin** and **acetylated monoglyceride**
INVENTOR(S): Sherman, Bernard Charles, 50 Old Colony Road, Willowdale, Canada M2L 2K1
PATENT ASSIGNEE(S): Sherman, Bernard Charles, Willowdale, Canada (non-U.S. individual)

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 6258783	B1	20010710	
	WO 9848779		19981105	
APPLICATION INFO.:	US 1999-403660		19991027	(9)
	WO 1998-CA408		19980429	
			19991027	PCT 371 date
			19991027	PCT 102(e) date

	NUMBER	DATE
PRIORITY INFORMATION:	NZ 1997-314702	19970429

DOCUMENT TYPE: Utility
FILE SEGMENT: GRANTED
PRIMARY EXAMINER: Jarvis, William R. A.
ASSISTANT EXAMINER: Kim, Vickie
LEGAL REPRESENTATIVE: Hughes, Ivor M., Hughes, Neil H., Sarkis, Marcelo K.
NUMBER OF CLAIMS: 7
EXEMPLARY CLAIM: 1
LINE COUNT: 374
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
CLM What is claimed is:

1. A pharmaceutical composition in the form of an emulsion preconcentrate comprising a **cyclosporin** dissolved in a solvent system consisting essentially of **acetylated monoglyceride** lipophilic solvents and a surfactant.

2. The composition of claim 1 in the form of a microemulsion preconcentrate.

3. The composition of claim 1 wherein the **acetylated monoglyceride** is a fully **acetylated monoglyceride** prepared from unsaturated monoglyceride.

4. The composition of claim 1 wherein the surfactant is a polyoxyethylene glycolated natural or hydrogenated vegetable oil.

5. The composition of claim 4 wherein the surfactant is polyoxyl 40 hydrogenated castor oil.

6. The composition of claim 1 wherein the surfactant is a polyoxyethylene-sorbitan-fatty acid ester.

7. The composition of claim 1 comprising two surfactants, one of which is a polyoxyethylene glycolated natural or hydrogenated vegetable oil and the second of which is a polyoxyethylene-sorbitan-fatty acid ester.

L10 ANSWER 2 OF 3 USPATFULL
ACCESSION NUMBER: 2000:61578 USPATFULL
TITLE: Cyclosporin-containing microemulsion preconcentrate composition
INVENTOR(S): Hong, Chung Il, East Amherst, NY, United States

L15 ANSWER 1 OF 12 USPATFULL
IN Sherman, Bernard Charles, 50 Old Colony Road, Willowdale, Canada M2L 2K1
PI US 6258783 B1 20010710
WO 9848779 19981105

L15 ANSWER 2 OF 12 USPATFULL
IN Sherman, Bernard Charles, 50 Old Colony Road, Willowdale, Ontario, Canada M2L 2K1
PI US 6159933 20001212

L15 ANSWER 3 OF 12 USPATFULL
IN Hong, Chung Il, East Amherst, NY, United States
Kim, Jung Woo, Seoul, Korea, Republic of
Choi, Nam Hee, Seoul, Korea, Republic of
Shin, Hee Jong, Kyeonggi-do, Korea, Republic of
Yang, Su Geun, Kyeonggi-do, Korea, Republic of
PI US 6063762 20000516

L15 ANSWER 4 OF 12 USPATFULL
IN Hong, Chung Il, East Amherst, NY, United States
Kim, Jung Woo, Seoul, Korea, Republic of
Choi, Nam Hee, Seoul, Korea, Republic of
Shin, Hee Jong, Kyeonggi, Korea, Republic of
Yang, Su Geun, Kyeonggi-do, Korea, Republic of
PI US 6028067 20000222

L15 ANSWER 5 OF 12 USPATFULL
IN Woo, Jong Soo, Suwon-shi, Korea, Republic of
PI US 5958876 19990928

L15 ANSWER 6 OF 12 USPATFULL
IN Hauer, Birgit, Lahr, Germany, Federal Republic of
Meinzer, Armin, Munzingen, Germany, Federal Republic of
Posanski, Ulrich, Freiburg, Germany, Federal Republic of
Richter, Friedrich, Schonbush-Urtenen, Switzerland
PI US 5916589 19990629

L15 ANSWER 7 OF 12 USPATFULL
IN Nudelman, Edward D., Seattle, WA, United States
PI US 5798386 19980825

L15 ANSWER 8 OF 12 USPATFULL
IN Cavanak, Thomas, Biel-Benken, Switzerland
PI US 5759997 19980602

L15 ANSWER 9 OF 12 USPATFULL
IN Cavanak, Thomas, Biel-Benken, Switzerland
PI US 5639724 19970617

L15 ANSWER 10 OF 12 USPATFULL
IN Woo, Jong S., Kyunggi-do, Korea, Republic of
PI US 5603951 19970218

L15 ANSWER 11 OF 12 USPATFULL
IN Woo, Jong S., Kyunggi-do, Korea, Republic of
PI US 5589455 19961231

L15 ANSWER 12 OF 12 USPATFULL
IN Hauer, Birgit, Lahr, Germany, Federal Republic of
Meinzer, Armin, Freiburg/Munzingen, Germany, Federal Republic of
Posanski, Ulrich, Freiburg, Germany, Federal Republic of
Richter, Friedrich, Schonbuhl-Urtenen, Switzerland

PI US 5342625 19940830

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L15 ANSWER 12 OF 12 USPATFULL

CLM What is claimed is:

1. A pharmaceutical composition comprising a **cyclosporin** as active ingredient, 1) a hydrophilic phase component comprising 1.1) a pharmaceutically acceptable di- or partial-ether of the formula R.sub.1. . .

. . . to claim 8 wherein said surfactant (3) comprises a polyoxyethylene glycolated natural or hydrogenated vegetable oil as surfactant and a **monoglyceride** as said co-surfactant.

14. The composition according to claim 11 comprising from 5 to 20% by weight of said **cyclosporin** based upon the total weight of the composition.

16. The composition according to claim 11 wherein the ratio of said **cyclosporin** to 1,2-propylene glycol is from 1:0.5 to 1:3 parts per weight.

20. The composition of claim 11 wherein the ratio of said **cyclosporin** to said component 3) is from 1:1 to 1:10 parts by weight.

21. The composition according to claim 1 comprising from 0.05 to 15% by weight of said **cyclosporin** based on the total weight of said composition, wherein said composition is in a form suitable for topical application.

22. The composition according to claim 21 comprising from 0.1 to 10% by weight of said **cyclosporin** based on the total weight of said composition.

24. The composition of claim 1, wherein said **cyclosporin** is Ciclosporin.

25. The composition of claim 1 wherein said **cyclosporin** is [Nva].sup.2 -Ciclosporin.

. . . comprises a fatty acid triglyceride; and 3) a surfactant which comprises a polyoxyethylene glycolated natural or hydrogenated vegetable oil and **monoglyceride**; wherein said composition is a microemulsion pre-concentrate capable, on contacting with water, of forming an oil-in-water microemulsion having an average. . .

PI US 5342625 19940830

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most preferably less than 1% water.

SUMM By use of suitable individual carrier ingredients or mixtures thereof, **emulsions** may be obtained in liquid or semi-solid form depending on, e.g., desired requirements for topical application.

SUMM Compositions for topical use may further comprise one or more consistency promoting agents, for example **microcrystalline** waxes, vegetable oils such as olive oils, corn oils and kernel oils, and vegetable oil derivatives including hydrogenated vegetable oils. . .

DETD **cyclosporine** 1.04 g;

DETD **cyclosporine** 1.04 g;

DETD **cyclosporine** 1.04 g;

DETD **cyclosporine** 1.04 g;

DETD **cyclosporine** 1.04 g;

DETD **cyclosporine** 5.20 g;

DETD **cyclosporine** 1.04 g;

DETD . . . the case of each of examples 1 to 7, the solution formed was readily dispersible in water to form an **emulsion** without precipitation of the **cyclosporine**.

DETD . . . done by performing a comparative bioavailability study in which capsules were ingested by human volunteers, blood samples were drawn and **cyclosporine** levels were measured. It was found that the extent of absorption of the composition of example 6 was substantially greater. . .

DETD . . . in various ways previously described, including, for example, their incorporation into gelatin capsules or tablets for oral ingestion, or into **emulsions** and various other forms for oral or topical use.

DETD The aforesaid examples use **cyclosporine** as the drug. However, similar compositions can be prepared using other drugs that are soluble in alcohols or in solvent. . .

CLM What is claimed is:

5. A composition according to claim 1 wherein said monocyclic non-polar peptide is **cyclosporine**.

ACCESSION NUMBER: 1998:150895 USPATFULL

TITLE: Pharmaceutical acceptable compositions containing an alcohol and a hydrophobic drug

INVENTOR(S): Sherman, Bernard C., 50 Oldcolony Road, Willowdale, Ontario, Canada M2L 2K1

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 5843891		19981201	
	WO 9425068		19941110	
APPLICATION INFO.:	US 1995-537697		19951027	(8)
	WO 1994-CA222		19940422	
			19951027	PCT 371 date
			19951027	PCT 102(e) date

	NUMBER	DATE
PRIORITY INFORMATION:	NZ 1993-247516	19930428

DOCUMENT TYPE: Utility

FILE SEGMENT: Granted

PRIMARY EXAMINER: Spivack, Phyllis G.

LEGAL REPRESENTATIVE: Nixon & Vanderhye P.C.

NUMBER OF CLAIMS: 17

EXEMPLARY CLAIM: 1

LINE COUNT: 578

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

CLM What is claimed is:

5. A composition according to claim 1 wherein said monocyclic non-polar peptide is **cyclosporine**.

ACCESSION NUMBER: 1998:150895 USPATFULL
TITLE: Pharmaceutical acceptable compositions containing an alcohol and a hydrophobic drug
INVENTOR(S): Sherman, Bernard C., 50 Óldcolony Road, Willowdale, Ontario, Canada M2L 2K1

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 5843891		19981201	
	WO 9425068		19941110	
APPLICATION INFO.:	US 1995-537697		19951027	(8)
	WO 1994-CA222		19940422	
			19951027	PCT 371 date
			19951027	PCT 102(e) date

	NUMBER	DATE
PRIORITY INFORMATION:	NZ 1993-247516	19930428

DOCUMENT TYPE: Utility
FILE SEGMENT: Granted
PRIMARY EXAMINER: Spivack, Phyllis G.
LEGAL REPRESENTATIVE: Nixon & Vanderhye P.C.
NUMBER OF CLAIMS: 17
EXEMPLARY CLAIM: 1
LINE COUNT: 578
COMMAND INTERRUPTED
REENTER FILE 'USPATFULL, CAPLUS, PCTFULL, JAPIO'
AND TRY AGAIN, OR ENTER '?' FOR MORE INFORMATION.

Your command did not complete due to a temporary system problem. To recover, reenter the file you are in now. Then, any command that is normally available to you may be used. No cost summary for the current file will be displayed. After reentering the current file you may retry your command. Also, you may wish to SAVE your search query. This can be done in any file. If you cannot access your current file, or if your command fails a second time, notify the Help Desk. Enter "HELP STN" for information on contacting the nearest STN Help Desk by telephone or by using the SEND command in STNMAIL file.

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L30 ANSWER 8 OF 15 USPATFULL

TI **Microemulsion preconcentrates** comprising cyclosporins

AB A pharmaceutical composition in the form of a **microemulsion preconcentrate** comprising a cyclosporin dissolved in a solvent system further comprising a hydrophobic component, a hydrophilic component, and a surfactant, wherein. . .

SUMM . . . of nonpolar polypeptides. as defined in the Merck Index, Eleventh Edition. One such cyclosporin is cyclosporin A, also known as " **cyclosporine**" and hereinafter referred to as " **cyclosporine**", known to be therapeutically active as an immunosuppressant.

SUMM U.S. Pat. No. 4,388,307 discloses compositions comprising **cyclosporine** in an **emulsion preconcentrate** that is not water-miscible, but forms an **emulsion** upon being mixed into gastrointestinal fluids. A commercial product that has been sold under the trademark "Sandimmune" is made according to U.S. Pat. No. 4,388,307, and, more specifically, comprises **cyclosporine** dissolved in a solvent system comprising ethanol, a vegetable oil and a surfactant. Although this composition was superior to previously. . .

SUMM **Emulsions** with droplet size of less than 2000 .ANG. are defined as "**microemulsions**". Compositions that, upon addition to water, disperse into **microemulsions** are called " **microemulsion preconcentrates**".

SUMM . . . 5,342,625 is now marketed under the trademark "Neoral", in the form of both a soft gelatin capsule which encloses the **microemulsion preconcentrate** and an oral liquid which is a **microemulsion preconcentrate** intended to be diluted into an aqueous drink before ingestion.

SUMM For both the soft gelatin capsules and the oral liquid, the labelling indicates that the "Neoral" **emulsion preconcentrate** comprises **cyclosporine** dissolved in ethanol and propylene glycol as hydrophilic solvents, corn oil as lipophilic (hydrophobic) solvent, and polyoxyl 40 hydrogzenated castor. . .

SUMM 2. The meiting point of the **microemulsion preconcentrate** is about 20.degree. C. so that it may solidify at room temperature. This means that the oral solution may have. . .

SUMM 3. Ethanol contributes to an undesirable taste of the **microemulsion preconcentrate**, so that, even after dilution into a sweetened drink, there is still a somewhat unpleasant taste.

SUMM . . . of cvciosporine is limited to about 100 mg per mL so that a soft gelatin capsules containing 100 mg of **cyclosporine** is larger than desirable and difficult to swallow.

SUMM International Publication Number WO 94/25068 discloses improved compositions in the form of **microemulsion preconcentrates** in which the principal solvent for the cyclosporin is an alcohol which is selected from alcohols having a boiling point. . .

SUMM In view of the difficulties with prior art compositions, the object of the invention is to enable **microemulsion preconcentrates** comprising cyclosporins which use combinations of excidients (i.e. inactive ingredients) not disclosed in the prior art, and therebv overcome some. . .

SUMM As with compositions of U.S. Pat. No. 5,342,625, compositions of the within invention take the form of **microemulsion preconcentrates** comprising a cyclosporin dissolved in a solvent system further comprising at least one hydrophobic solvent, at least one hydrophilic solvent. . .

SUMM More particularly the invention is a pharmaceutical composition in the form of a **microemulsion preconcentrate** comprising a cyclosporin dissolved in a solvent system further comprising a hydrophobic component, a hydrophilic component and a surfactant,

wherein. . .

SUMM A **microemulsion preconcentrate** comprising a cyclosporin must contain a hydrophobic solvent and surfactant.

SUMM xiv) **Monoglycerides**; e.g. glycerol monooleate, glycerol monopalmitate and glycerol monostearate; for example as known and commercially available under the trade names Myvatex, Myvaplex and Myverol, and **acetylated**, e.g. mono- and di-**acetylated** mono-glycerides; for example as known and commercially available under the trade name Myvacet.

SUMM Especially where oral administration is contemplated, compositions in accordance with the invention may comprise end dosage forms for administration as **microemulsion preconcentrates**. For example the **microemulsion preconcentrate** may be directly used as liquid for oral ingestion, parenteral use, or topical application or it may be encapsulated into. . .

SUMM However, the present invention also provides pharmaceutical compositions in which the **microemulsion preconcentrate** is further processed into a **microemulsion**. Thus where oral admniistration is practised, **microemulsions** obtained, e.g. by diluting a **microemulsion preconcentrate** with water or other aqueous medium (for example, a sweetened or flavoured preparation for drinking), may be employed as formulations for drinking. Similarly, where topical application is foreseen, compositions comprising a **microemulsion preconcentrate**, a thickening agent and water will provide an aqueous **microemulsion** in gel, paste, cream or like form.

SUMM Compositions in accordance with the present invention, whether **microemulsion preconcentrates** or **microemulsions**, may be employed for administration in any appropriate manner and form; e.g. orally, as liquids or granules or in unit. . .

SUMM . . . the invention will, of course, vary considerably depending on the particular type of composition concerned; e.g,. whether it is a **microemulsion preconcentrate** or **microemulsion** , the route of administration, and so forth. The relative proportions will also vary depending on the particular ingredients employed and. . .

DETD

cyclosporine	1.0
ethanol	0.8
dl-alpha-tocopherol acetate	1.2
polyoxyl 40 hydrogenated castor oil	7.0
	10.0

DETD

cyclosporine	1.0
benzyl alcohol	0.5
polyethylene glycol 300	2.0
di-alpha-tocopherol acetate	1.0
polyoxyl 40 hydrogenated castor oil	5.5
	10.0

DETD

cyclosporine	1.0
ethanol	0.8
dl-alpha-tocopherol	1.2
polyoxyl 40 hydrogenated castor oil	7.0
	10.0

DETD

cyclosporine	1.0
propylene carbonate	2.5
dl-alpha-tocopherol	1.5
polyoxyl 40 hydrogenated castor oil	5.0
	10.0

DETD

cyclosporine	1.0
propylene carbonate	2.0
dl-alpha-tocopherol	2.0
polyoxyl 40 hydrogenated castor oil	5.0
	10.0

DETD

cyclosporine	1.0
propylene carbonate	3.0
Coviox T70	1.5
polyoxyl 40 hydrogenated castor oil	5.4
	10.9

DETD . . . 6, when a quantity of the composition was added to water and upon shaking, the composition dispersed to form a **microemulsion** .

DETD The composition of each of examples 1 to 6 is a **microemulsion preconcentrate** directly useable as drops for oral ingestion or as a liquid for opthalmic or topical use. Alternatively, these compositions may. . . in various ways previously described, including, for example, their incorporation into gelatin capsules or tablets for oral ingestion, or into **microemulsions** and various other forms for oral or topical use.

DETD . . . point of the composition is well below 20.degree. C., so that these compositions are especially well suited for use as **preconcentrates** to be added to an aqueous medium and used as a drink, regardless of whether the drink is warm or. . .

CLM What is claimed is:
1. A pharmaceutical composition wherein said composition is a **microemulsion preconcentrate** comprising a cyclosporin dissolved in a solvent system, said solvent system comprising a hydrophilic component, a hydrophobic component, and a. . .
11. A composition according to claim 1 wherein the cyclosporin is **cyclosporine**.

ACCESSION NUMBER: 1999:159981 USPATFULL
TITLE: **Microemulsion preconcentrates** comprising cyclosporins
INVENTOR(S): Sherman, Bernard Charles, Willowdale, Canada
PATENT ASSIGNEE(S): Sherman, Bernard C., Weston, Canada (non-U.S. individual)

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 5998365		19991207	
	WO 9722358		19970626	
APPLICATION INFO.:	US 1998-77803		19980615	(9)
	WO 1996-CA803		19961203	
			19980615	PCT 371 date
			19980615	PCT 102(e) date

	NUMBER	DATE
PRIORITY INFORMATION:	NZ 1995-280689	19951215
DOCUMENT TYPE:	Utility	
FILE SEGMENT:	Granted	
PRIMARY EXAMINER:	Moezie, F. T.	
LEGAL REPRESENTATIVE:	Nixon & Vanderhye P.C.	
NUMBER OF CLAIMS:	14	
EXEMPLARY CLAIM:	1	
LINE COUNT:	524	

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L30 ANSWER 5 OF 15 USPATFULL

TI **Emulsion preconcentrate** comprising a cyclosporin and **acetylated monoglyceride**

AB Pharmaceutical compositions in the form of an **emulsion preconcentrate** or **microemulsion preconcentrate** which comprise a cyclosporin as active ingredient, **acetylated monoglyceride** as lipophilic solvent, a surfactant, and optionally a hydrophilic solvent.

SUMM . . . of nonpolar polypeptides, as defined in the Merck Index, Twelfth Edition. One such cyclosporin is cyclosporin A, also known as "**cyclosporine**" and hereinafter referred to as "**cyclosporine**", known to be therapeutically active as an immunosuppressant.

SUMM . . . solvent system that comprises at least one lipophilic (hydrophobic) solvent and a surfactant, so that the composition disperses into an **emulsion** when mixed into gastrointestinal fluid or other aqueous medium.

SUMM Such compositions are called "**emulsion preconcentrates**".

SUMM . . . that has been sold under the trademark "Sandimmune" is made according to U.S. Pat. No. 4,388,307, and, more specifically, comprises **cyclosporine** dissolved in a solvent system comprising ethanol as hydrophilic solvent, a vegetable oil as lipophilic solvent, and a surfactant. The. . .

SUMM It is also disclosed that compositions according to U.S. Pat. No. 5,342,625, when added to water, disperse into **emulsions** with droplet size of less than 2000,.ANG., which is smaller than obtained with prior art compositions, thus leading to improved. . .

SUMM **Emulsions** with droplet size of less than 2000 .ANG. are defined as "**microemulsions**". Compositions that, upon addition to water, disperse into **microemulsions** are called "**microemulsion preconcentrates**".

SUMM Canadian Patent 2072509 discloses **microemulsion preconcentrates** comprising a cyclosporin dissolved in a carrier which comprises:

SUMM . . . patent 2072509 is now marketed under the trademark "Neoral", in the form of both an oral liquid which is a **microemulsion preconcentrate** intended to be diluted into an aqueous drink before ingestion, and a soft gelatin capsule containing the **microemulsion preconcentrate**.

SUMM For both the soft gelatin capsules and the oral liquid, the labelling indicates that the "Neoral" **emulsion preconcentrate** comprises **cyclosporine** dissolved in ethanol and propylene glycol as hydrophilic solvents, corn oil glycerides as lipophilic (hydrophobic) solvent, and polyoxyl 40 hydrogenated. . .

SUMM 2. Ethanol contributes to an undesirable taste of the **microemulsion preconcentrate**, so that, even after dilution into a sweetened drink, there is still a somewhat unpleasant taste.

SUMM International Publication Number W094/25068 discloses improved compositions in the form of **microemulsion preconcentrates** in which the principal solvent for the cyclosporin is an alcohol which is selected from alcohols having a boiling point. . . solubility in water of under 10 g per 100 g at 20.degree. C. Because such alcohols are good solvents for **cyclosporine**, they eliminate the need for ethanol. Preferred alcohols, within the scope of the disclosure of W094/25068, are saturated alkyl alcohols. . .

SUMM New Zealand Patent Application No. 280689 discloses improved **microemulsion preconcentrates** in which a cyclosporin is dissolved in a solvent system comprising a lipophilic (hydrophobic solvent), a hydrophilic solvent and a. . .

SUMM . . . found that such advantages can be achieved and the drawbacks of the prior art surmounted when using as lipophilic solvent **acetylated monoglycerides**. **Acetylated monoglycerides** are inexpensive and exhibit ideal properties for use as lipophilic (hydrophobic) solvent in cyclosporin **emulsion preconcentrates**.

SUMM The present invention thus provides a pharmaceutical composition in the form of an **emulsion preconcentrate** comprising a cyclosporin dissolved in a solvent system comprising **acetylated monoglycerides**, and a surfactant.

SUMM In a further embodiment such pharmaceutical composition is in the form of a **microemulsion preconcentrate**.

SUMM As aforesaid, an essential component of an **emulsion preconcentrate** is a lipophilic solvent, and it has been found that **acetylated monoglycerides** function surprisingly well as lipophilic solvent in cyclosporin **emulsion preconcentrates**.

SUMM It will be understood that **acetylated monoglycerides** consist of glycerol esterified with fatty acids at one of the three hydroxyl functions, with the other two hydroxyls replaced. . .

SUMM **Acetylated monoglycerides** are sold in the United States under the tradename "Myvacet" by Eastman Chemical Products Inc. They are made by reacting. . .

SUMM Fully **acetylated monoglycerides** prepared from unsaturated **monoglycerides** are liquids at room temperature. In this context, the phrase "fully **acetylated**" is intended to mean having a minimum acetylation of about 96%.

SUMM Fully **acetylated monoglycerides** are currently available from Eastman Chemical Product Inc. under the designations Myvacet 9-08 and Myvacet 9-45. For

SUMM In comparison to other ingredients used in the prior art as lipophilic solvent, these **acetylated monoglycerides** offer the following advantage:

SUMM 4. They become readily dispersible into **emulsions** or **microemulsions** upon inclusion of a suitable surfactant.

SUMM Because of the aforesaid properties, acceptable **emulsion preconcentrates** or **microemulsion preconcentrates** can be made using only the active drug (i.e. a cyclosporin), **acetylated monoglycerides**, and a surfactant.

SUMM . . . per 100 g in water at 20.degree. C.) as co-solvent. This is because suitable hydrophilic solvents are more efficient than **acetylated monoglycerides** as solvents for cyclosporin. Inclusion of a suitable hydrophilic solvent can thus reduce the total amount of solvent needed, thereby. . .

SUMM . . . preferred hydrophilic solvents are propylene glycol and propylene carbonate. Propylene carbonate is most preferred because of its complete miscibility with **acetylated monoglycerides**.

SUMM The fact that a **microemulsion preconcentrate** can be made using **acetylated monoglyceride** as lipophilic solvent and propylene carbonate as hydrophilic solvent, despite the fact that they are miscible with each other, is. . .

SUMM . . . which is meant a compound with both lipophilic and hydrophilic properties, which improves the dispersibility of the composition into an **emulsion** or **microemulsion** in water.

SUMM . . . surfactant as co-surfactant can reduce the total amount of surfactant needed, without loss of effectiveness in enabling dispersion into an **emulsion** or **microemulsion**.

SUMM Compositions in accordance with the invention may comprise dosage forms for direct administration as **emulsion preconcentrates** or **microemulsion preconcentrates**. For example, an **emulsion preconcentrate** or **microemulsion preconcentrate** may be directly used as liquid for oral

ingestion, parenteral use, or topical application or it may be encapsulated into. . .

SUMM However, the present invention also provides pharmaceutical compositions in which the **emulsion preconcentrate** or **microemulsion preconcentrate** is further processed into an **emulsion** or a **microemulsion**. Thus where oral administration is practised, **emulsions** or **microemulsions** obtained, e.g. by diluting a **preconcentrate** with water or other aqueous medium (for example, a sweetened or flavoured preparation for drinking), may be employed as formulations for drinking. Similarly, where topical application is intended, compositions comprising an **emulsion preconcentrate**, a thickening agent, and water will provide an aqueous **emulsion** in gel, paste, cream or like form.

SUMM Compositions in accordance with the present invention, whether **emulsion preconcentrates**, **microemulsion preconcentrates**, **emulsions**, or **microemulsions**, may be employed for administration in any appropriate manner and form; e.g. orally, parenterally, topically; or rectally.

SUMM . . . the invention will, of course, vary considerably depending on the particular type of composition concerned; e.g. whether it is an **emulsion preconcentrate**, **microemulsion preconcentrate**, **emulsion**, or **microemulsion**, the route of administration, and so forth. The relative proportions will also vary depending on the particular ingredients employed and. . .

DETD

Cyclosporine	1.0
Myvacet 9-45	6.0
Cremophor RH40	3.7
	10.7

DETD Then 1 g of the resulting **emulsion preconcentrate** was transferred to another test tube, about 20 mL of water was added, and the test tube was shaken.. The **preconcentrate** dispersed to form an **emulsion**.

DETD Then 1 g from the resulting **emulsion preconcentrate** in each test tube was transferred to another test tube, about 20 mL of warm (37.degree. C.) water was added,. . . and the test tube was shaken to disperse the 1 g of the composition in the water to form an **emulsion** or **microemulsion**. The resultant **emulsions** or **microemulsions** were then compared for clarity by measuring the light transmittance through a 1 cm cell at 600 nm. A higher transmittance indicates a smaller droplet size and hence, a finer **emulsion** or **microemulsion**.

DETD

Example No.	1	2	3	4	5	6	7	8
Cyclosporine	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Myvacet 9-45	2.7	2.5	2.3	2.1	2.7	2.5	2.3	2.1
Propylene	1.6	1.6	1.6. . .					

DETD As aforesaid, the transmittance is that of an **emulsion** or **microemulsion** made by dispersing 1 g of the composition in about 20 mL of warm (37.degree. C.) water.

DETD In each case, the density of the **preconcentrate** was about 1.07 g/mL, so that each mL of the **preconcentrate** contained about 100 mg of **cyclosporine**.

DETD . . . The compositions of all of examples 1 to 8 thus all gave higher transmittance than Neoral, which indicates that the **microemulsions** are at least as fine as obtained with Neoral.

CLM What is claimed is:

1. A pharmaceutical composition in the form of an **emulsion preconcentrate** comprising a cyclosporin dissolved in a solvent system consisting essentially of **acetylated monoglyceride** lipophilic solvents and a surfactant.

2. The composition of claim 1 in the form of a **microemulsion preconcentrate**.

3. The composition of claim 1 wherein the **acetylated monoglyceride** is a fully **acetylated monoglyceride** prepared from unsaturated **monoglyceride**.

ACCESSION NUMBER:	2001:107866 USPATFULL
TITLE:	**Emulsion preconcentrate** comprising a cyclosporin and **acetylated monoglyceride**
INVENTOR(S):	Sherman, Bernard Charles, 50 Old Colony Road, Willowdale, Canada M2L 2K1
PATENT ASSIGNEE(S):	Sherman, Bernard Charles, Willowdale, Canada (non-U.S. individual)

	NUMBER	KIND	DATE	
PATENT INFORMATION:	US 6258783	B1	20010710	
	WO 9848779		19981105	
APPLICATION INFO.:	US 1999-403660		19991027	(9)
	WO 1998-CA408		19980429	

L4 ANSWER 3 OF 4 CAPLUS COPYRIGHT 2003 ACS
AN 1990:558601 CAPLUS
DN 113:158601
TI Absorption of polyethylene glycols 600 through 2000: the molecular weight dependence of gastrointestinal and nasal absorption
AU Donovan, Maureen D.; Flynn, Gordon L.; Amidon, Gordon L.
CS Coll. Pharm., Univ. Michigan, Ann Arbor, MI, 48109-1065, USA
SO Pharmaceutical Research (1990), 7(8), 863-8
CODEN: PHREEB; ISSN: 0724-8741
DT Journal
LA English
CC 63-5 (Pharmaceuticals)
Section cross-reference(s): 1
AB Polyethylene glycols (PEGs) 600, 1000, and 2000 were used to study the mol. wt. permeability dependence in rat nasal and gastrointestinal mucosa. Absorption of the PEGs was measured by following their urinary excretion over a 6-h collection period. HPLC methods were used to sep. and quantitate the individual oligomeric species present in the PEG samples. The permeabilities of both the gastrointestinal and the nasal mucosa exhibited similar mol. wt. dependencies. The steepest absorption dependence for both mucosa occurs with the oligomers of PEG 600, where the extent of absorption decreases from approx. 60 to near 30% over a mol. wt. range of <300 **daltons**. Differences in the absorption characteristics between the two sites appear in the mol. wt. range spanned by **PEG 1000**. For these oligomers, the mean absorption from the nasal cavity is approx. 14%, while that from the gastrointestinal tract is only 9%. For PEG 2000, mean absorption decreases to 4% following intranasal application and <2% following gastrointestinal administration. Within the **PEG 1000** and 2000 samples, however, very little mol. wt. dependency is seen among the oligomers. In the range studied, a distinct mol. wt. cutoff was not apparent at either site.
ST polyethylene glycol absorption mol wt; nose polyethylene glycol absorption mol wt; gastrointestinal absorption polyethylene glycol mol wt
IT Molecular weight
(of macromol. drugs, gastrointestinal and nasal absorption response to, delivery system in relation to)
IT Digestive tract
Nose
(polyethylene glycol absorption by, mol. wt. effect on, drug delivery system in relation to)
IT Pharmaceutical dosage forms
(nasal, for macromol. drugs, mol. wt. effect on drug absorption in relation to)
IT 25322-68-3, Polyethylene glycol
RL: USES (Uses)
(gastrointestinal and nasal absorption of, mol. wt. effect on, drug delivery system in relation to)

=>

L4 ANSWER 2 OF 4 CAPLUS COPYRIGHT 2003 ACS
AN 1998:70638 CAPLUS
DN 128:129088
TI Effect of addition of polyethylene glycol on the moisture transfer and waterproof properties of foam-finished nylon fabrics
AU Yen, Meng-Shung; Yeh, Tseng-Chin
CS Department of Textile Engineering, National Taiwan University of Science and Technology, Taipei, 10672, Taiwan
SO Journal of Polymer Research (1997), 4(4), 253-260
CODEN: JPOREP; ISSN: 1022-9760
PB Polymer Society
DT Journal
LA English
CC 40-5 (Textiles and Fibers)
AB The effects of the addn. of polyethylene glycol (PEG) within the coated film on the water vapor permeability and waterproof properties of the foam-coated fabrics were investigated. Foaming solns. added with PEG had lower surface tension than those without, and the viscosity and stability of the foaming soln. varied with PEG of different mol. wt. When PEG is of 1,000 **daltons** (**PEG 1000**), the viscosity and stability of the foaming soln. was the highest among mol. wts. ranging from 400 to 16,000, whereas the surface tension was the lowest. The stability would rise proportionally with viscosity if the viscosity of the foaming soln. is between 13,610 cps and 13,960 cps. When **PEG 1000** was added, the particle size of the foaming soln. was smaller, followed by PEG 600. But when PEG 4000 or ethylene glycol (EG) was added, the particle size was bigger. The introduction of **PEG 1000** to the foaming soln. produced better water vapor permeability and waterproof properties. Fabrics coated with foaming soln. to which **PEG 1000** was added, had smaller and more micropores in the coated film. Coated film without the addn. of PEG had less micropores, and that with the addn. of EG or PEG 4000 had large pores with nonhomogenous pore sizes. These results were confirmed by SEM observation.
ST polyethylene glycol moisture transfer coated fabric; nylon fabric waterproof foam coated PEG
IT Polyurethanes, uses
RL: MOA (Modifier or additive use); PEP (Physical, engineering or chemical process); PRP (Properties); PROC (Process); USES (Uses)
(coatings; polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT Polyamide fibers, uses
RL: PRP (Properties); TEM (Technical or engineered material use); USES (Uses)
(fabrics, coated; polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT Polyamides, uses
RL: PEP (Physical, engineering or chemical process); POF (Polymer in formulation); PRP (Properties); PROC (Process); USES (Uses)
(fabrics; polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT Coating materials
Waterproofing
(polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT Polyoxyalkylenes, uses
RL: MOA (Modifier or additive use); PEP (Physical, engineering or chemical process); PRP (Properties); PROC (Process); USES (Uses)
(polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT 25038-54-4, Polyamide 6, uses
RL: PEP (Physical, engineering or chemical process); POF (Polymer in

formulation); PRP (Properties); PROC (Process); USES (Uses)
(fabrics; polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
IT 107-21-1, Ethylene glycol, uses 25322-68-3, Polyethylene glycol
RL: MOA (Modifier or additive use); PEP (Physical, engineering or chemical process); PRP (Properties); PROC (Process); USES (Uses)
(polyethylene glycol addn. in relation to moisture transfer and waterproof properties of foam-finished nylon fabrics)
RE.CNT 20 THERE ARE 20 CITED REFERENCES AVAILABLE FOR THIS RECORD
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